UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,141	09/27/2004	Reddy Bandi Parthasaradhi	H1089/20013	1984

3000 7590 09/27/2007

CAESAR, RIVISE, BERNSTEIN,
COHEN & POKOTILOW, LTD.
11TH FLOOR, SEVEN PENN CENTER
1635 MARKET STREET
PHILADELPHIA, PA 19103-2212

EXAMINER	
SHIAO, REI TSANG	

ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
09/27/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@crbcp.com

Office Action Summary	Application No.	Applicant(s)	
	10/509,141	PARTHASARADHI ET AL.	
	Examiner	Art Unit	
	Rei-tsang Shiao, Ph.D.	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *12-18 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/19/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment of claims 19 in the amendment filed on July 19, 2007 is acknowledged. Claims 1-20 are pending in the application.

Information Disclosure Statement

2. Applicant's Information Disclosure Statement, filed on July 19, 2007 has been considered. Please refer to Applicant's copy of the 1449 submitted herein.

Responses to Election/Restriction

3. The requirement is still deemed proper and is therefore made FINAL.

Responses to Amendment/Arguments

4. Applicant's arguments regarding the rejection of claims 3-4 and 8-9 under 35 U.S.C. 112, second paragraph have been fully considered and they are persuasive, in part. Since the X-ray powder diffraction data between claim 3 and 8 is distinct, therefore he rejection of claims 3 and 8 under 35 U.S.C. 112, second paragraph has been withdrawn herein. However, the X-ray powder diffraction data of Figure 1 or Figure 2 has not been incorporated into claims 4 and 9 respectively, the rejection of claims 4 and 9 under 35 U.S.C. 112, second paragraph is maintained.

5. Applicant's arguments regarding the rejection of claim 19 under 35 U.S.C. 112, first paragraph have been fully considered and they are not persuasive.

Since applicants do not provide direct evidence that the instant pharmaceutical compositions comprising candesartan cilexetil form III are stable after the processes of preparing (i.e., i.e., mixing, grinding, and compressing, or converting into the instant form IV), the rejection of claim 19 under 35 U.S.C. 112, first paragraph is maintained. The Examiner have advanced a reasonable basis for questioning the adequacy of the disclosure for the enablement of pharmaceutical composition, see Brittain's publication, pages 348-361.

Once USPTO personnel have advanced a reasonable basis for questioning the adequacy of the disclosure, it becomes incumbent on the applicant to rebut that challenge and factually demonstrate that his or her application disclosure is in fact sufficient. See In re Doyle, 482 F.2d 1385, 1392, 179 USPQ 227, 232 (CCPA 1973); In re Scarbrough, 500 F.2d 560, 566, 182 USPQ 298, 302 (CCPA 1974); In re Ghiron, supra. See also MPEP § 2106, paragraph V.B.2 and § 2164 - § 2164.08(c).<

2162 Policy Underlying 35 U.S.C. 112, First Paragraph.

Applicants are requested to provide evidence to overcome the rejection.

6. Applicant's arguments regarding the rejection of claim 19 under 35 U.S.C. 102(b) over Naka et al. US 5,196,444 have been fully considered and they are not persuasive. It is noted that an acceptable carrier can be water and therefore the instant crystal forms of the instant compound dissolves in the composition (i.e., aqueous solution), and it will exist in free form and not as a crystal form or a solvate form. Amendment of claim 19 as a solid pharmaceutical composition would obviate the rejection.

7. Applicant's arguments regarding the rejection of claims 1-11 and 19 under 35 U.S.C. 103(a) over Naka et al. US 5,196,444 in view of Brittain's publication have been fully considered and they are persuasive, in part. Since Naka et al. do not disclose the 1,4-dioxane solvate of candesartan cilexetil compound, therefoe the rejection of claims 1-2 under 35 U.S.C. 103(a) over Naka et al. US 5,196,444 in view of Brittain's publication has been withdrawn herein. However, Naka et al. disclose crystalline form of the instant candesartan cilexetil compound, and claims 3-11 and 19 are drawn to crystalline candesartan cilexetil compound/compositions and their processes. Therefore claims 3-11 and 19 still render obviousness over Naka et al. '444 in view of Brittain's publication. The rejection of claims 3-11 and 19 under 35 U.S.C. 103(a) over Naka et al. US 5,196,444 in view of Brittain's publication is maintained.

8. Applicant's arguments with respect to claims 1-11 and 19 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 and 19 are rejected under 35 U.S.C. 103(a) as being obvious over Naka et al. US 5,196,444 in view of publication of U.S. Department of Health and Human Service, Guidance for Industry, May 15, 2001.

Applicant claim a candesartan cilexetil 1,4-dioxane solvate, and its pharmaceutical compositions, see claim 1 and 19. Dependent claims 2-11 and 19 further limit a number of scope of claim 1, i.e., candesartan cilexetil compound is a

crystalline compound with an X-ray power diffraction pattern data, or candesartan cilexetil 1,4-dioxane solvate is candesartan cilexetil form III.

Determination of the scope and content of the prior art (MPEP §2141.01)

Naka et al. disclose crystalline form of candesartan cilexetil solvate (i.e., 1-(Cyclohexyloxycarbonyloxy)ethyl 2-ethoxy-1-[[2'-(1H-tetrazol-5-yl)biphenyl-4-yl]methyl]benzimidazole-7-carboxylate or its solvate or solvent form), and its pharmaceutical composition, see working example 7 of columns 7-10.

Determination of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and Naka et al. is that Naka et al. is silent on the X-ray diffraction data of the instant compound, or Naka et al. is silent on the instant solvent 1,4-dioxane. However, Naka et al. do disclose suitable solvent for the instant candesartan cilexetil compound, and solvents are not limited to a number of exemplified solvents, see lines 21-35 of column 9.

Guidance for Industry, a publication of U.S. Department of Health and Human Service, discloses 1,4-doxane is suitable pharmaceutical solvent for a pharmaceutical compound (i.e., candesartan cilexetil).

Finding of prima facie obviousness-rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art would find the instant claims 1-11 and 19 prima facie obvious **because** one would be motivated to employ the compounds/ compositions of Naka et al. and the inherent teachings of Guidance for Industry to obtain the instant crystalline form of the same compound candesartan cilexetil or its solvate or solvent form and its pharmaceutical compositions, wherein the instant compound is in a crystalline form (i.e., form III). Further, changing the form, purity or other characteristic of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art, see In re Cofer, 148 U.S.P.Q. 268 (CCPA 1966). It is noted that obviousness to try selected from a number of choice (i.e., solvents listed in Table 2 in page 9 of Guidance for Industry), which have been suggested to one skilled in the art, see *KSR International Co.* v. *Teleflex Inc.*, 550 U.S.-, 82 USPQ2d 1385 (2007). Therefore, absent a showing of unobvious and superior properties in terms of mechanic benefits, the instant claimed crystalline forms and its compositions of known compounds would have been suggested to one skilled in the art. Dependent claims 2-11 and 19 are also rejected along with claim 1 under 35 U.S.C. 103(a).

The motivation to obtain the claimed crystalline form of the compound candesartan cilexetil or its pharmaceutical composition derives from known Naka et al. pharmaceutically useful compounds/compositions and teachings of Guidance for Industry with the expectation of obtaining a pharmaceutically useful benefit, such as longer shelf life, stability, enhanced deliverability, etc., would possess similar activities (i.e., agents treating hypertension) to that which is claimed in the reference.

Claim Objections

10. Claim 6 is objected to as depending on a non-elected subjected matter (i.e., amorphous form). It is suggested that applicants amend the claims to obviate the objection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rei-tsang Shiao whose telephone number is (571) 272-0707. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rei-tsang Shiao, Ph.D.
Patent Examiner
Art Unit 1626

September 17, 2007